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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,256	06/28/2006	John Kim	13564-105027US1	3316
65989 7590 03/20/2009 KING & SPALDING 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036-4003				
EXAMINER SHAHNAN SHAH, KHATOOL S				
ART UNIT 1645		PAPER NUMBER		
NOTIFICATION DATE 03/20/2009		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

### Office Action Summary

**Application No.**

10/562,256

**Applicant(s)**

KIM ET AL.

**Examiner**

Khatol S. Shahnan-Shah

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 14-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 21 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF-08)
- Paper No(s)/Mail Date 12/21/2005
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicants' amendments of 12/02/2008 are acknowledged. Claims 6 and 11 have been amended.

***Status of Claims***

2. Claims 1-15 are pending and under consideration.

***Drawings***

3. The drawings submitted 12/21/2005 have been accepted by the examiner.

***Specification***

4. The disclosure is objected to because of the following informalities:

Use of multiple abbreviations such as GCMP, GBSP, GYMP, GWMP, MWCO, SEC-MALLS etc has been noted in this specification. Full name and description of these abbreviations are required when they appear first time in the specification.

The use of the trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. Appropriate corrections are required.

***Information Disclosure Statement***

5. The information disclosure statement filed 12/21/2005 has been considered. An initialed copy is enclosed.

***Election/Restrictions***

6. Applicants' election with traverse of 12/02/2008 is acknowledged. Applicants have elected group III, claims 11-15 which are drawn to a conjugate vaccine. For election of species applicants elected *Streptococcus* group B. The traversal is on the ground(s)

that do not lack unity of invention, because the amended claims are linked by a common special technical feature to form a single general inventive concept. The special technical feature in this case is an immunogenic conjugate comprising a carbohydrate (e.g., a capsular polysaccharide) covalently bonded to tetanus toxin Fragment C. This is not found persuasive because:

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature-linking groups I-III appears to be tetanus toxin C fragment. However, Fairweather et al. (US 5,443,966) prior art of record, international search report teach a process for producing fragment C of tetanus toxin and conjugate vaccine which comprises fragment C and **may include other antigens to provide a multivalent vaccine** ( see column 3, lines 20-24). Therefore, the technical feature linking the inventions of groups I-III does not constitute a special technical feature as defined by the PCT Rule 13.2, as it does not define a contribution over the prior art. As set forth above, each of group I-III has a special technical feature that is not required for the other groups.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11-13 are under consideration. Claims 1-10 and 14-15 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Wessels et al. (Infection and Immunity, vol. 66, no. 5, pp. 2186-2192, May 1998) from hereon called Wessels I.

The claims are drawn to a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin Fragment C, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B.

Wessels I teaches a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B, (see abstract, page 2186 and 2187). Wessels I does not explicitly disclose Fragment C; however this fragment is inherently included in whole length tetanus toxin. The prior art anticipates the claimed invention.

9. Claims 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Wessels et al. (Journal of Clinical Investigation, vol. 86, pp. 1428-1433 November 1990) from hereon called Wessels II.

The claims are drawn to a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin Fragment C, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B.

Wessels II teaches a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B, (see abstract, page 1428 and 1429). Wessels II does not explicitly disclose Fragment C; however this fragment is inherently included in whole length tetanus toxin. The prior art anticipates the claimed invention.

10. Claims 11-13 are rejected under 35 U.S.C. 102 (b) as being anticipated by Michon et al. (In *Streptococci* and Host. (Ed). Horaud et al. Plenum Press, New York, pp. 847-850, 1997) IDS of record.

The claims are drawn to a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin Fragment C, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B.

Michon et al. teach a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B, (see abstract, page 847). Michon et al. do not explicitly disclose Fragment C; however this fragment is inherently included in whole length tetanus toxin. The prior art anticipates the claimed invention.

11. Claims 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Jennings et al. US 5,993,825

The claims are drawn to a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin Fragment C, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B.

Jennings et al. teach a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin, wherein said antigen is a capsular polysaccharide of

*Streptococcus* group B; (see abstract, columns 1, 3, 4, 5 and claims). Jennings et al. do not explicitly disclose Fragment C; however this fragment is inherently included in whole length tetanus toxin. The prior art anticipates the claimed invention.

**12.** Claims 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Michon et al. WO 2004/0111027 A1

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The claims are drawn to a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin Fragment C, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B.

Michon et al. teach a conjugate vaccine comprising an antigen that has been conjugated to Fragment C of tetanus toxin, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B, (see abstract and claims). Michon et al. teach Fragment C of tetanus toxin (see figures and claims 5, 36, 43 and pages 4 and 6). The prior art anticipates the claimed invention.

**13.** Claims 11-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Michon et al. US 6,602,508 B2.

**Note:** The specification defines Fragment C as 52 kilo Dalton fragment of tetanus toxin.

The claims are drawn to a conjugate vaccine comprising an antigen that has been conjugated to tetanus toxin Fragment C, wherein said antigen is a capsular polysaccharide of *Streptococcus* group B.

Michon et al. ('508) teach multivalent GBS conjugate vaccines comprising the multivalent conjugates, wherein different types of GBS capsular polysaccharides including types I, II, III, IV and V

are conjugated to a single protein, such as tetanus toxin (see abstract, claims, and columns 3 and 9). Michon *et al.* ('508) teach fragments of tetanus toxin with molecular weight of 15, 33 and 51 kilo Dalton). Michon *et al.* teach Fragment C i.e. the 51 kilo Dalton fragment (see column 9). The prior art anticipates the claimed invention.

***Status of the Claims***

14. No claims are allowed.

***Conclusion***

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol Shahnan-Shah whose telephone number is 571-272-0863. The examiner can normally be reached on Monday-Friday 7:30 AM-5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on 571-272-0956.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Khatol S Shahnan-Shah/

Examiner, Art Unit 1645

March 14, 2009

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645